COMPARISON OF ONSET AND DURATION OF SENSORY AND MOTOR BLOCKADE BETWEEN INTRATHECAL 0.5% ISOBARIC BUPIVACAINE WITH 25 MICROGRAMS FENTANYL AND 0.5% HYPERBARIC BUPIVACAINE WITH 25 MICROGRAMS FENTANYL FOR INFRAUMBILICAL SURGERIES- A ONE-YEAR HOSPITAL BASED RANDOMISED CONTROLLED TRIAL

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ABSTRACT

BACKGROUND

In spinal anaesthesia, commonly used drugs are isobaric bupivacaine and hyperbaric bupivacaine. Commonly opioids like fentanyl are used as adjuvants with local anaesthetics to improve analgesic intensity and to achieve faster onset and prolonged duration. This study aims at comparing isobaric bupivacaine-fentanyl and hyperbaric bupivacaine-fentanyl primarily, in terms of onset and duration of sensory and motor blockade and secondarily, in terms of haemodynamic changes and associated complications.

MATERIALS AND METHODS

Eighty patients belonging to American Society of Anaesthesiologists I and II undergoing infraumbilical surgeries under spinal anaesthesia were randomised into two groups. Group A received 3 ml of 0.5% isobaric bupivacaine with 25 micrograms fentanyl, while Group B received 3 ml of 0.5% hyperbaric bupivacaine with 25 micrograms fentanyl. Student's unpaired t-test and the $\chi 2$ test were used to analyse the results, using the SPSS version 11.5 software.

RESULTS

The mean onset of sensory block was significantly faster in Group B (3.55 ± 0.96 min) than in Group A (5.70 ± 0.69 min). The mean duration of sensory block was significantly longer in Group B (189.65 ± 9.58 min) than in Group A (129.08 ± 3.47 min). The mean onset of motor block was significantly faster in Group B (4.78 ± 0.80 min) than in Group A (7.83 ± 0.78 min). The mean duration of motor block was significantly longer in Group B (204.55 ± 12.46 min) than in Group A (171.18 ± 4.31 min). Isobaric bupivacaine-fentanyl mixture was associated with better haemodynamic stability as compared with hyperbaric bupivacaine-fentanyl mixture.

CONCLUSION

Intrathecal isobaric bupivacaine-fentanyl mixture is associated with lesser duration of both sensory and motor blockade, thereby enabling quicker recovery from anaesthesia and also better haemodynamic stability as compared with hyperbaric bupivacaine fentanyl mixture for infraumbilical surgeries.

KEYWORDS

Bupivacaine, Fentanyl, Hyperbaric, Isobaric, Spinal Anaesthesia.

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BACKGROUND

Spinal anaesthesia is a commonly performed procedure for infraumbilical surgeries. The advantages are an awake and spontaneously breathing patient, minimal drug costs, reduction of usage of multiple drugs. It is a simple, effective and safe technique. Regional anesthesia techniques have seen numerous modifications over the last two decades with addition of newer anesthetic agents combined with adjuvant. Very few studies have been done comparing isobaric and hyperbaric bupivacaine with fentanyl. Hence with this study we attempt at comparing Isobaric bupivacaine-fentanyl and Hyperbaric buivacaine-fentanyl in terms of onset and duration of sensory and motor blockade for infraumbilical surgeries under spinal anaesthesia.

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MATERIALS AND METHODS

The present study was conducted in the Department of Anaesthesiology, KLE's Dr. Prabhakar Kore Hospital and Medical Research Center, Nehru Nagar, Belagavi during the period of January 2017 to December 2017.

After obtaining the approval of ethical committee and written informed consent, a total of 80 patients undergoing elective infraumbilical surgeries under spinal anaesthesia were included in the study. Patients between the age group of 18-60 yrs.', belonging to ASA Grade I and II scheduled for elective infraumbilical surgeries at K.L.E`S Dr. PrabhakarKore Hospital and Medical Research Center, Nehru Nagar, Belagavi between January 2017 to December 2017 were included. The patients excluded were those who refused spinal anaesthesia, who were hypovolaemic, uncooperative, pregnant patients and those with spinal deformity.

Patients were randomised based on computer generated randomisation table into two groups.

Group A received 3 ml of 0.5% isobaric bupivacaine with 0.5 ml (25 micrograms) of fentanyl making a total volume of 3.5 ml of drug.

Group B received 3 ml of 0.5% hyperbaric bupivacaine with 0.5 ml (25 micrograms) of fentanyl making a total volume of 3.5 ml of drug.

A thorough Pre-Anaesthetic Evaluation was done. In the preoperative holding area, a wide bore I.V. access was secured and patients were preloaded with ringer lactate 10ml/kg half an hour before induction of anaesthesia. Anaesthetic techniques were standardized for all patients.

Inside the operation theatre, the patient were shifted onto the operating table. Standard non – invasive monitors were attached and baseline Heart Rate, BP, SpO_2 was recorded.

Patient were then put in left lateral position and under strict aseptic precautions, L3-L4 space was identified. Skin was infiltrated with 2 ml 0f 2% lignocaine. Using 23G Quincke spinal needle L3-L4 subarachnoid space was identified after confirming free flow of clear CSF.

Group A: 3 ml of 0.5% isobaric bupivacaine with 0.5 ml (25 micrograms) of fentanyl making a total volume of 3.5 ml of drug was injected in L3-L4 subarachnoid space.

Group B: 3ml of 0.5% hyperbaric bupivacaine with 0.5 ml (25 micrograms) of fentanyl making a total volume of 3.5ml of drug was injected in L3-L4 subarachnoid space.

Patients were then immediately placed in supine position. Intraoperative and postoperative assessments were performed. The following parameters were monitored/measured:

Sensory Blockade was assessed by pinprick in mid axillary line every minute till T_{10} block occurs, following which it will be assessed at 10-minute intervals for next 2 hrs. and at 15-minute intervals beyond 2 hrs till full regression occurs.

Sensory block onset was taken as the time of administration of drug to the time taken for sensory blockade till T_{10} dermatome and highest sensory dermatome blocked was recorded. Duration of sensory block was taken as the time for regression to two dermatomes from the highest dermatome reached and time for regression to S_2 would be recorded.

Surgery was allowed to start once T_{10} dermatome was blocked but GA was induced if this does not happen in 30 minutes. Such cases were labeled as Block failure and excluded from final analysis.

Motor Blockade was assessed immediately after sensory block assessment using a Modified Bromage scale.

Bromage 0: - Free movement of legs and with ability to raise extended leg.

Bromage 1: - Inability to raise extended leg and knee flexion is decreased, but full flexion of ankle and feet is present.

Bromage 2: -Inability to raise leg or flex knees, flexion of ankle and feet present.

Bromage 3: -Inability to raise leg, flex knee or ankle or move toes.

Motor block onset was be taken as the time to reach modified Bromage score 3 and total duration of motor block will be taken as the time for return to modified Bromage score 0.

In case patient doesn't attain Bromage score of 3, the highest score attained was documented.

Following surgery patient were not put on regular analgesics. Time for first rescue analgesia was noted and were treated with inj. Diclofenac sodium 75 mg added to 100 ml of normal saline.

Heart rate, Blood pressure and SpO_2 were monitored throughout the surgery.

Blood pressure and Heart rate were recorded at 2, 4, 6, 8, 10, 15, 20, 25, 30 minutes and every 15 minutes till the end of surgery. Hypotension was defined as decrease in systolic B.P. by 20% from baseline values or a systolic B.P. less than 90 mm of Hg and was treated with incremental intravenous boluses of mephentermine 5 to 10 mg and a bolus administration of 250 ml of Ringer Lactate solution over 10 mins. Bradycardia was defined as decrease in heart rate less than 50 beats per minute and was treated with intravenous Atropine 0.6 mg.

Supplementary oxygen was given through face mask. Any side effects which occurred were duly documented

Statistical Analysis

Student unpaired 't test was used to find significance of study parameters on continuous scale between the two groups. Chi - square test was used to find association between different classes of variables. A p – value <0.05 was considered statistically significant.

RESULTS

A total of 80 patients undergoing infraumbilical surgeries under spinal anaesthesia were randomly allocated into one of the two groups based on a computer generated randomisation chart-

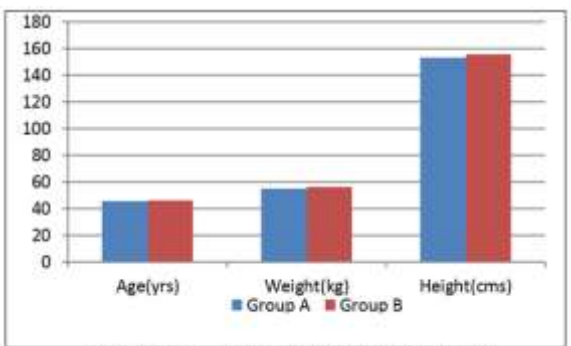
Group A: 3 ml of 0.5% isobaric bupivacaine with 0.5 ml (25 micrograms) of fentanyl making a total volume of 3.5 ml of drug was injected in L3-L4 subarachnoid space.

Group B: 3 ml of 0.5% hyperbaric bupivacaine with 0.5 ml (25 micrograms) of fentanyl making a total volume of 3.5 ml of drug was injected in L3-L4 subarachnoid space.

Data obtained was coded and analysed as below.

	Group A		Group B		p-Value
	Mean	Standard Deviation	Mean	Standard Deviation	
Age (Years)	45.55	13.34	46.38	11.26	0.7659
Weight (Kgs.)	54.58	4.02	56.38	4.47	0.0621
Height (cms)	153.30	5.52	155.57	5.57	0.0710

Table 1. Mean Age, Weight and Height

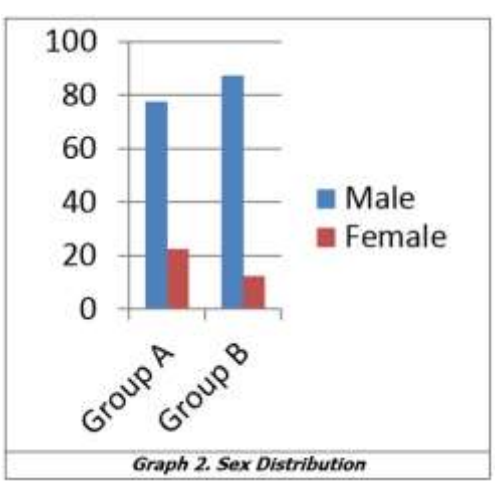


Graph 1. Mean Age, Weight and Height

In the present study we found no statistically significant difference between Group A and Group B with regards to mean age (45.55 ± 13.34 and 46.38 ± 11.26 years respectively; p = 0.7659), mean weight (54.58 ± 4.02 and 56.38 ± 4.47 kgs. respectively; p = 0.0621) and mean height (153.30 ± 5.52 and 155.57 ± 5.57 cms respectively; P =0.0710).

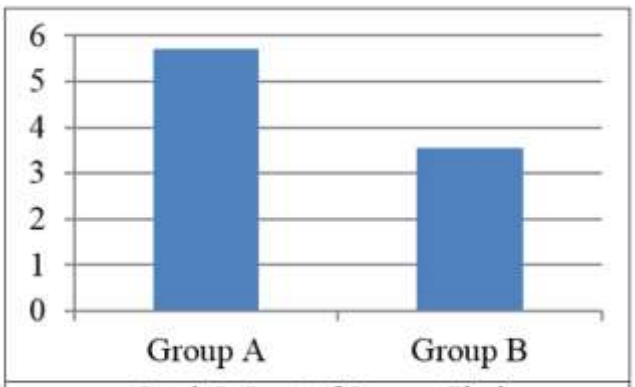
	Group A	%	Group B	%	Total
Female	9	22.5	5	12.5	14
Male	31	77.5	35	87.5	66
Total	40	100	40	100	80

Table 2. Sex Distribution

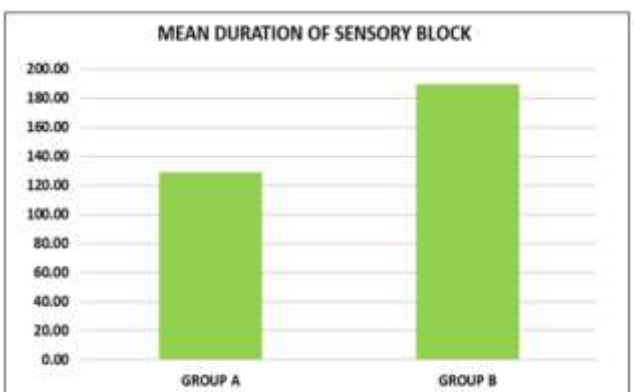


Graph 2. Sex Distribution

In this study 77.5% were males and 22.5% were females in Group A and 87.5% were males and 12.5% were females in Group B, suggesting both the groups had comparable demographic characteristics.



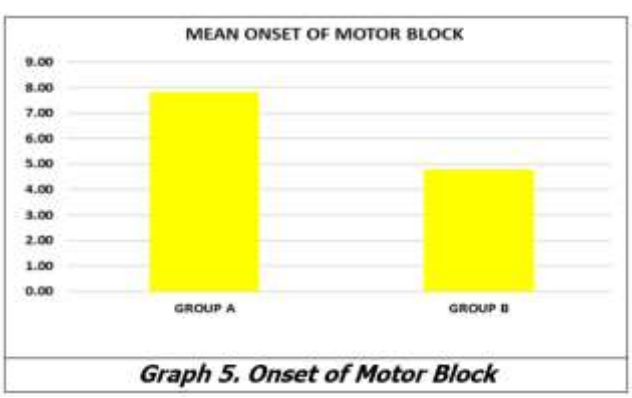
Graph 3. Onset of Sensory Block



Graph 4. Duration of Sensory Block

In our study, mean onset of sensory blockade was faster in Group B (3.55 ± 0.96 min) than in Group A (5.70 ± 0.69 min)

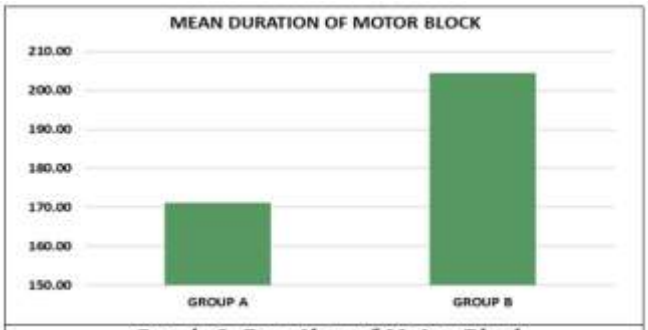
The mean duration of sensory blockade was longer in Group B (189.65 ± 9.58 min) than in Group A (129.08 ± 3.47 min).



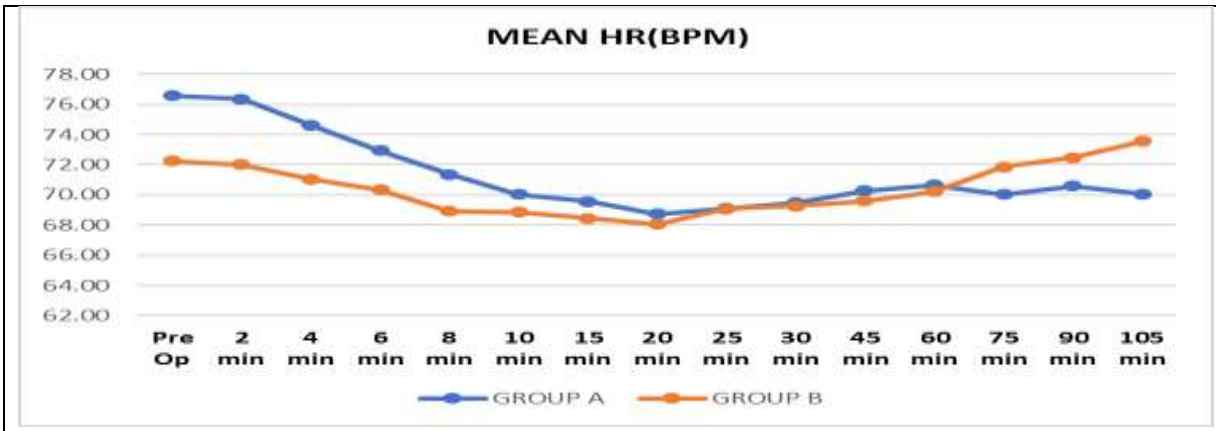
Graph 5. Onset of Motor Block

In the present study, mean onset of motor block was faster in Group B (4.78±0.80 min) than Group A (7.83 ± 0.78 min)

The mean duration of motor block was longer in Group B (204.55± 12.46 min) than Group A (171.18 ± 4.31 min).

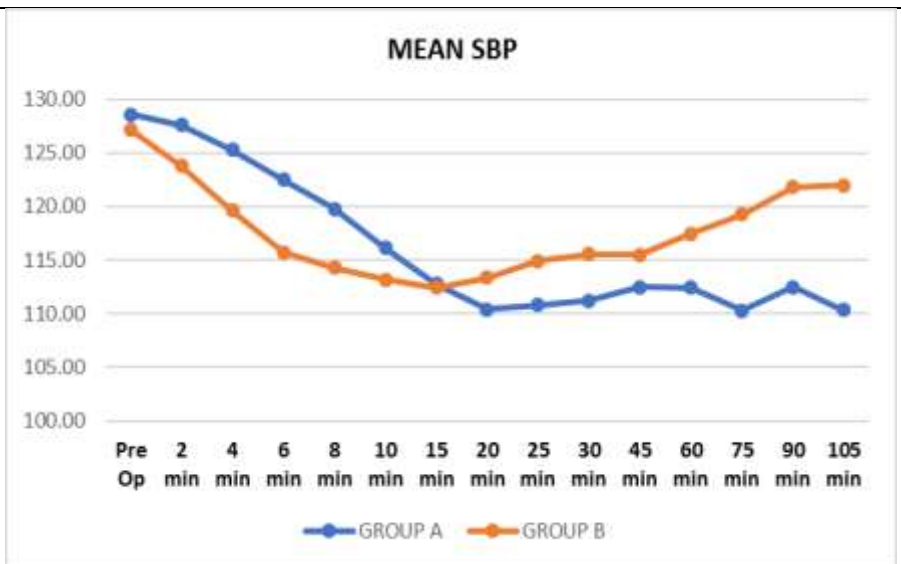


Graph 6. Duration of Motor Block



Graph 7. Comparison of Mean Heart Rate at Different Intervals (bpm)

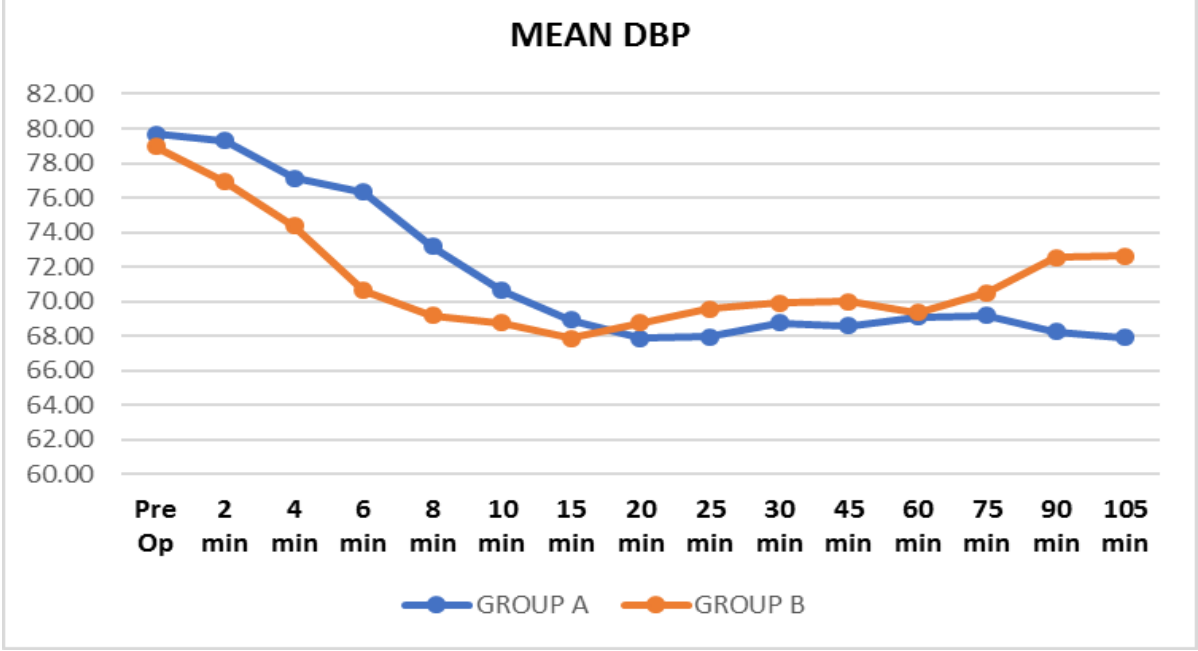
In this study the mean heart rate in the pre-operative phase was 76.60 ±6.74 bpm in Group A and 72.28 ± 6.47 bpm in Group B. The heart rate fell to 70.65± 6.60 bpm at 60 minutes in Group A while it fell to 70.23± 7.10 bpm at 60 minutes in Group B.



Graph 8. Comparison of Systolic Blood Pressure at Different Intervals (mmHg)

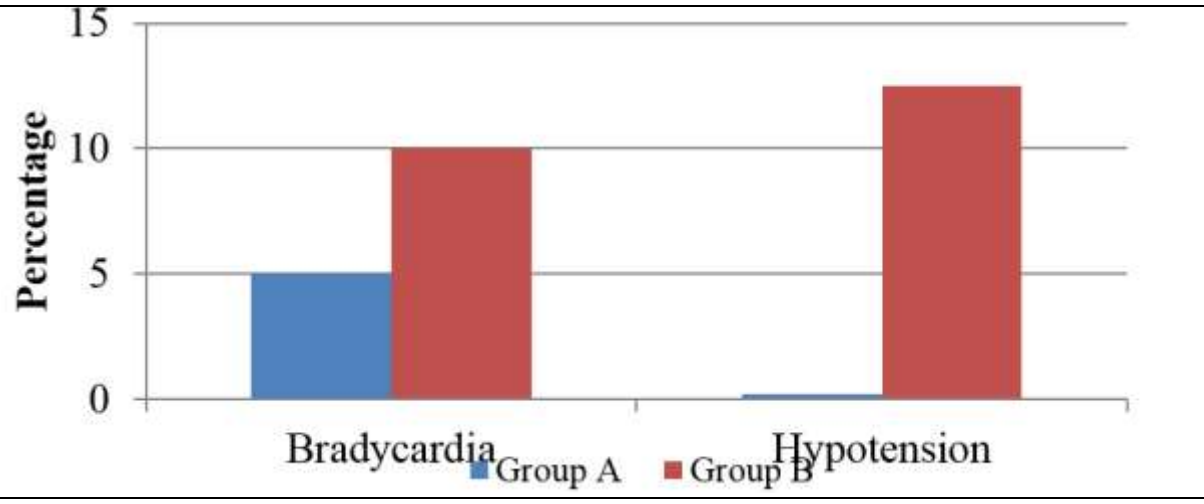
In this study the mean systolic BP in the pre-operative phase was 128.60 ± 9.23 mm of Hg in Group A and 127.15 ±8.95 in Group B.

The systolic BP fell to 112.40 ± 8.54 mm of Hg at 60 minutes and 110.33 ± 6.87 mm of Hg at 105 minutes in Group A while it fell to 117.45 ± 8.86 mm of Hg at 60 minutes and 122.00 ± 9.09 mm of Hg at 105 minutes in Group B.



Graph 9. Comparison of Diastolic Blood Pressure at Different Intervals (mmHg)

In this study the mean diastolic BP in the pre-operative phase was 79.70 ± 10.45 mm of Hg in Group A and 78.95 ± 8.13 mm of Hg in Group B. The diastolic BP fell to 69.10 ±5.66 mm of Hg at 60 minutes and 67.93 ±5.95 mm of Hg at 105 minutes in Group A while it fell to 69.35 ± 4.52 mm of Hg at 60 minutes and 72.61 ± 4.06 mm of Hg at 105 minutes in Group B.



Graph 10. Complications/ Side Effects Observed (Percentage)

In the present study, 5% of patients in Group A and 10% of patients in Group B developed bradycardia.
12.5% of patients in Group B developed Hypotension.
None of the patients in either group developed Nausea and vomiting or respiratory depression.

DISCUSSION

Spinal administration of local anaesthetics is the choice of anaesthesia technique for infraumbilical surgeries. Spinal anaesthesia has a quick onset, provides good relaxation with adequate sensory blockade. Hence it is one of the most commonly performed anaesthetic procedures in today's times.

Bupivacaine, the most commonly used local anaesthetic in spinal anaesthesia, is a racemic mixture (50: 50) of its two enantiomers, levobupivacaine, S (−) isomer and dextro bupivacaine, R (+) isomer. Adverse reactions involving central nervous system and cardiovascular system have been reported in literature. These adverse reactions have been attributed to the R (+) isomer of bupivacaine.

The advantages of using opioids like fentanyl with local anaesthetics are sensory blockade can be achieved with fewer pulmonary complications, early return of bowel functions, early discharge from hospital.

In the present study, hemodynamic stability was better in Group A compared to Group B. The time of onset

of sensory blockade and motor blockade was faster in Group B compared to Group A. The durations of sensory and motor blockade were prolonged in Group B compared to Group A which was clinically significant.

A study conducted by Madhusudan Upadya et al in January 2016 compared intrathecal hyperbaric bupivacaine-fentanyl mixture and isobaric bupivacaine-fentanyl mixture in common urological procedures.[1] One hundred patients belonging to American society of Anaesthesiologists grade I and grade II undergoing urological procedures were randomized into two groups. Group 1 received 3ml of 0.5% bupivacaine with 25 micrograms fentanyl while Group II received 3ml of 0.5% hyperbaric bupivacaine with 25 micrograms fentanyl. The parameters measured included onset and duration of motor and sensory blockade, heart rate, blood pressure, respiratory rate. They concluded that isobaric bupivacaine-fentanyl mixture was found to provide adequate anaesthesia with minimal incidence of haemodynamic instability. The results were similar to our study.

In a study conducted by Axelsson KH et al, A double blind study of motor blockade in lower limbs, they concluded that Glucose-free bupivacaine solution gave significantly longer complete motor blockade than bupivacaine solution without glucose. The muscle strength of hip flexion and knee extension returned significantly later after administration of the glucose-free anaesthetic solution. A shorter total regression time (all movements) in the glucose-free group than in the group that received glucose in the anaesthetic solution meant that the patients could be mobilized after almost the same length of time, 6.5-7 h, irrespective of which solution had been given - that is, not until 1.5-2 h had elapsed after Bromage grade 0.[2]

Another study by Seewal R, et al in January 2007 evaluated effect of addition of different doses of fentanyl intrathecally to 0.5% hyperbaric bupivacaine on perioperative analgesia and subarachnoid block characteristics in lower abdominal surgery: A dose response study.[3] A population of 60 patients belonging to ASA I and II were randomized to receive a spinal anaesthetic with 2.2 ml of 0.5% hyperbaric bupivacaine saline (control group) or fentanyl 10, 20, 30 or 40 micrograms. The conclusion was that in a non-obstetric population receiving spinal anaesthetic for lower abdominal surgery, addition of 10 micrograms fentanyl to 0.5% hyperbaric bupivacaine significantly improves the quality and duration of analgesia. No further advantage occurs if the dose of fentanyl is increased upto 40 micrograms

Another study by MochamatHelmi, et al in February 2014 compared intrathecal use of isobaric and hyperbaric bupivacaine during lower abdominal surgery.[4] Sixty patients with ASA I and II, undergoing elective lower abdominal surgeries with the estimation in duration no longer than 120 minutes were enrolled. Patients were randomized with sealed envelope method into 2 groups. Group I received 4 ml of 0.5% isobaric bupivacaine while group 2 received 4 ml of 0.5% hyperbaric bupivacaine. Neither the anaesthesiologist performing SAB and collecting perioperative data nor the patients were aware of the used solution. They concluded that isobaric bupivacaine produced more rapid onset and longer duration compared to hyperbaric bupivacaine. This was contrary to our findings where hyperbaric bupivacaine had a faster onset and a longer duration of analgesia.[5]

In another study comparing intrathecal isobaric and hyperbaric bupivacaine anaesthesia for lower abdominal surgeries, 20 mg bupivacaine was used without additives. There was no statistically significant haemodynamic variation between the two groups. It was found that the onset of analgesia and motor blockade was faster with isobaric bupivacaine and the duration of analgesia was prolonged with isobaric bupivacaine, which was contrary to our findings where hyperbaric bupivacaine had a faster onset and a longer duration of analgesia.[5]

In a study conducted by Abuzaid S et al, The influence of diamorphine on spinal anaesthesia induced with isobaric 0.5% bupivacaine, they concluded that addition of 1 mg diamorphine to intrathecal 0.5% bupivacaine produced a prolonged and satisfactory analgesia in more than half the patients undergoing lower limb arterial or inguinal surgery, and the analgesic requirements of the remainder during the first postoperative 24 h were much less than those who received bupivacaine alone. In the urological surgery set there were no significant differences between the group who received bupivacaine and diamorphine, and the group who received bupivacaine alone.[6]

In a Cochrane analysis comparing six studies including 394 patients with intrathecal hyperbaric and isobaric bupivacaine,[4] the results were almost similar to our study. It was found that hyperbaric bupivacaine had rapid onset of analgesia and requirement for supplemental analgesia were also less. However, variability in the dose, use of adjuvant drugs and differences in the technique used for regional anaesthesia should be taken into consideration.[7]

In a study conducted by Hallworth et al, 150 patients undergoing elective cesarean delivery were randomized to receive a hyperbaric, isobaric, or hypobaric intrathecal solution of 10 mg bupivacaine during spinal anesthesia induced in either the sitting or right lateral position. After an intrathecal injection using a combined-spinal technique, patients were placed in the supine wedged position. They determined the densities of the three intrathecal solutions from a previously validated formula and measured using a DMA-450 density meter. Data collection included sensory level, motor block, episodes of hypotension, and ephedrine use. Statistical analysis included analysis of variance and Cuzick's trend. In the lateral position, baricity had no effect on the spread of sensory levels for bupivacaine compared to the sitting position, where there was a statistically significant difference in spread with the hypobaric solution producing higher levels of analgesia than the hyperbaric solution ($P = 0.002$). However, the overall differences in maximal spread only differed by one dermatome, with the hyperbaric solution achieving a median maximum sensory level to T3 compared with T2 for the isobaric and

hypobaric solutions. Motor block was significantly (P = 0.029) reduced with increasing baricity and this trend was significant (P = 0.033) for the lateral position only. Hypotension incidence and ephedrine use increased with decreasing baricity (P = 0.003 and 0.004 respectively), with the hypobaric sitting group having the most frequent incidence of hypotension (76%) as well as cervical blocks.[8]

In a study conducted by Pitkanen et al, Possible correlations between age and certain characteristics of spinal blockade with plain bupivacaine were investigated in 124 patients, ages ranging from 15 to 92 yr. Three millilitre of 0.5% solution (sp. gr. 1.000 at 37 degrees C) was injected at the L3-L4 interspace. There were great individual variations in all age groups, but the maximum spread of analgesia increased with age, although the correlation was poor (P less than 0.05). The spread of analgesia to L2 and L3 segments in the oldest patients (greater than or equal to 70 yr) was about twice as fast as that in the youngest (less than 30 yr). Complete motor blockade of the lower extremities developed most rapidly in the oldest patients (greater than or equal to 80 yr; mean 11 min), while in patients younger than 50 yr the mean time to complete motor block was approximately doubled. The mean sensory recovery of the two uppermost segments and the mean sensory recovery of the S1 segment did not correlate significantly with age.[9]

Our study results correlated with the studies by Madhusudan Upadya et al.[1] Hemodynamic stability was better with isobaric bupivacaine-fentanyl group compared to Hyperbaric bupivacaine-fentanyl group.

CONCLUSION

0.5% hyperbaric bupivacaine with fentanyl is significantly more potent than 0.5% isobaric bupivacaine with fentanyl in terms of onset and duration of sensory and motor block whereas, the haemodynamic parameters including HR, SBP and DBP are more stable in 0.5% isobaric bupivacaine with fentanyl than 0.5% hyperbaric bupivacaine with fentanyl in patients undergoing infraumbilical surgery under spinal anaesthesia.

Intrathecal isobaric bupivacaine-fentanyl mixture is associated with lesser duration of both sensory and motor blockade, thereby enabling quicker recovery from anaesthesia and also with better haemodynamic stability for infraumbilical surgeries as compared with hyperbaric bupivacaine fentanyl mixture.

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